

## **REMARKS**

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

Claims 17 - 38 are pending in this application. Claims 21 – 32 and 36 - 37 have been amended in response to Examiner's 35 USC § 112, second paragraph rejection by incorporating specific SEQ ID NOs as suggested by the Examiner.

Claim 38 has been amended to indicate that the first antibody is an antibody capable of binding phospho-IRS-1 or phospho-IRS-2. Support for this amendment may be found at, for example, paragraphs [0075-0077].

The Applicants aver that none of the amendments introduces new subject matter as support may be found throughout the specification and respectfully request entry of the claims as amended.

Each of the rejections set forth in the Action are addressed separately below.

### **I. 35 USC § 102(b) Rejections:**

Claims 17 – 33 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No: 5,593,678 (hereinafter “‘678”). The Applicants respectfully traverse.

The Examiner states at page 2, item 4 of the Action that “[t]he ‘678 patent teaches a polyclonal antibody that would bind SEQ ID NOs: 1-4 when phosphorylated but not when unphosphorylated (see particularly column 10, lines 62-65).”

The Applicants maintain that the ‘678 patent is not anticipatory in that it merely mentions the use of anti-phosphoserine antibodies. The ‘678 patent fails to teach SEQ ID NOs: 1-4 nor does it teach insulin receptor substrates 1/2. The Examiner's attention is directed to column 16, lines 16 – 37, which specifically identifies vanadate as having insulin mimetic properties. As described therein, vanadate mimics the activities of insulin. However, an insulin mimetic is not the same as insulin substrate receptors 1/2 and the ‘678 patent neither teaches nor suggests that an antibody to the mimetic could bind to the mimetic's substrate receptor.

The Applicants respectfully submit that the ‘678 patent is not anticipatory in that it

fails to teach all of the elements and limitations of Claims 17 – 33. As such, Applicants respectfully request withdrawal of the 35 USC § 102(b) rejection of Claims 17-33.

Claims 17 – 32 and 34 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No: 5,807,702 (hereinafter “‘702”). The Applicants respectfully traverse.

The Examiner states at page 2, item 5 of the Action that “[t]he ‘702 patent teaches a monoclonal antibody that would bind SEQ ID NOs: 1-4 when phosphorylated but not when unphosphorylated (see particularly column 13, lines 45-47).”

The Applicants respectfully submit that the ‘702 patent is not anticipatory. The ‘702 patent is directed to methods of producing phosphorylated, recombinant human  $\beta$ -casein. The Examiner’s attention is directed to column 3, lines 60 – 63 which states “[t]ransmembrane glycoproteins that acquire covalent palmitate after synthesis include the insulin, .beta..sub.2 -adrenergic and transferrin receptors.” This is the only instance in the ‘702 patent discussing any insulin receptors. The Applicants submit that the ‘702 patent fails to teach SEQ ID NOs: 1-4 nor does it show that the anti-phosphoserine antibody used therein would be capable of binding to insulin substrate receptors 1/2.

The Applicants maintain that the ‘702 patent is not anticipatory in that it fails to teach all of the elements and limitations of Claims 17 – 32 and 34. As such, Applicants respectfully request withdrawal of the 35 USC § 102(b) rejection of Claims 17-32 and 34.

## **II. 35 USC § 103(a) Rejections:**

Claims 36 - 38 stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,593,678 or U.S. Patent No. 5,807,702 in view of U.S. Patent No. 4,208,479 (hereinafter “‘479”). The Applicants respectfully traverse.

The Examiner points out at page 3, item 7 of the Action that “[t]he ‘479 patent teaches that kits allow for substantial convenience in performing assays... .” The Applicants submit that the ‘479 patent, in conjunction with either ‘678 or ‘702 does not teach the instant invention in that the ‘479 patent merely teaches the use of kits and fails to correct the deficiencies of the ‘678 or ‘702 patents in that the ‘479 patent fails to teach SEQ ID NOs: 1-4 specifically or anti-phosphoserine antibodies capable of binding to

insulin receptor substrates 1/2 in general.

The Applicants maintain that the '479 patent, in conjunction with either '678 or '702 does not make the instant invention obvious in that it fails to teach all of the elements and limitations of Claims 36 - 38. As such, Applicants respectfully request withdrawal of the 35 USC § 103(a) rejection of Claims 36 - 38.

### **III. 35 USC § 112, first paragraph Rejections:**

Claim 38 stands rejected under 35 USC § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicants respectfully traverse.

The Examiner's attention is directed to paragraphs [0040 - 0045 and 0063 - 0069] (including the references cited therein), Examples 1 & 2, and Figs. 11, 12, & 14 which *in toto* provide written support and describe the procedures for detecting PKC theta activity in full compliance with the requirements of 35 USC § 112, first paragraph.

The Applicants submit that the procedures for optimization of the assays are neither onerous nor require undue experimentation. Furthermore, the Applicants maintain that the internal references cited above in response to the lack of written support rejection provide sufficient information regarding levels of PKC theta expression so as to significantly reduce the amount of initial experimentation required for assay optimization.

As such, Applicants respectfully request withdrawal of this 35 USC § 112, first paragraph rejection of Claim 38.

Claim 38 additionally stands rejected under 35 USC § 112, first paragraph for failing to comply with the written description requirement.

The Applicants have amended Claim 38 *supra* thereby rendering Examiner's rejection moot.

The claim has been amended to indicate that the first antibody is an antibody of the invention capable of binding phospho-IRS-1 or phospho-IRS-2 as supported by

paragraphs [0075 - 0077], most specifically, paragraph [0077]. As such, Applicants respectfully request withdrawal of this 35 USC § 112, first paragraph rejection of Claim 38.

**IV. 35 USC § 112, second paragraph Rejections:**

Claims 21-38 stand rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 21 – 32 and 36 - 37 have been amended in response to Examiner's much appreciated suggestion to incorporate the specific SEQ ID NOs. associated with the specific serine positions. As such, Applicants request withdrawal of the rejection of Claims 21-38 under 35 USC § 112, second paragraph.

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### CONCLUSIONS

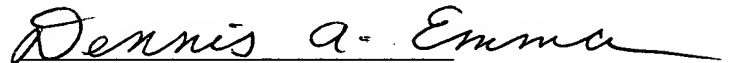
On the basis of the preceding amendments and remarks, this application is believed to be in condition for allowance. Accordingly, reconsideration of the claims as amended and its allowance are kindly requested.

A request for a Three (3) Month Extension of Time, up to and including May 2, 2008, pursuant to 37 C.F.R. §1.136 is hereby requested. The Examiner is authorized to charge any fees applicable in the instant, as well as in future communications, to Deposit Account No. 50-1774, Ref No: CST-209. Such an authorization should be treated as a constructive petition for extension of time in the concurrent as well as future replies.

The Examiner is encouraged to call the undersigned to facilitate prosecution.

Respectfully submitted,

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